

### **REMARKS**

This Amendment is made in response to the Final Action mailed September 4, 2008. Claims 7 and 8 were previously cancelled. Claim 5 is cancelled herein. Claim 1 has been amended. Accordingly, claims 1-4, 6, 9 and 10 remain pending in this application. Applicants believe that these amendments place the claims into condition for allowance, or, into better condition for appeal. Entry of the amendments herein and reconsideration and withdrawal of the objections to and rejections of this application are respectfully requested in view of the amendments, and further, in view of the following remarks.

Preliminarily, Applicants note that claim 1 has been amended to clarify that the anhydrous tooth whitening composition dries from its liquid state *in situ* to form an adherent film which sticks firmly to the teeth. Support for this amendment can be found on page 3, lines 13-15, and page 6, lines 22-26, of the instant specification. Further, claim 1 has been amended to clarify that the film-forming agent consists essentially of a water-insoluble film-forming agent which is ethyl cellulose.

Claims 1-6 and 10 have been rejected under 35 U.S.C. §103(a), as being unpatentable over U.S. Patent Application publication number US 2004/0086468 (now U.S. Patent 6,893,629), published May 6, 2004, to Prosise et al. ("Prosise"). In particular, the Action asserts that Prosise teaches a tooth whitening delivery system comprising a PVP-hydrogen peroxide complex, glycerol, hydroxypropylmethyl cellulose, ethyl cellulose and ethanol (see, paragraphs [0015] and [0017]). Reconsideration and withdrawal of the rejection are respectfully requested.

Applicants submit that the amount of film forming component present in Prosise does not fall within the scope of the present claims. Claim 1 discloses 5 to 30% w/w of the film forming component, wherein the film forming component is a water-insoluble film forming agent which is ethyl cellulose, and a solvent thereof. Furthermore, according to the three examples described in Prosise, the composition ingredients are mixed together, poured into a film-forming apparatus wherein the solvent is allowed to evaporate, forming a cast film, which film is cut into dry strips for application to the teeth. Indeed, throughout Prosise, it is taught that the film be flexible and malleable, which film generally maintains its integrity throughout the bleaching process. This is in contrast to the instant inventive composition which is applied to the teeth as an anhydrous liquid, and then allowed to dry *in situ* to form an adherent film which sticks firmly to the teeth.

There is absolutely no teaching or suggestion in Prosise of an anhydrous liquid tooth whitening composition comprising a peroxide-containing compound and an orally acceptable carrier wherein the carrier includes a humectant, a bioadhesive agent, and from 5 to 30% w/w of a film-forming component consisting essentially of a water-insoluble film-forming agent which is ethyl cellulose and a solvent for the film-forming agent, wherein the composition dries *in situ* to form an adherent film which sticks firmly to the teeth. Therefore, a *prima facie* case of obviousness has not been established. Reconsideration and withdrawal of the rejection under Section 103(a) are requested.

Claim 9 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Prosise in view of U.S. Patent No. 6,517,350, granted February 11, 2003, to Diasti et al. ("Diasti"). In particular, the Examiner asserts that Diasti teaches a tooth whitening compound with a carrier selected for adhering to the person's teeth; and that the composition can be applied to the teeth by methods including painting or coating. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 9 is directed to a method of whitening the teeth with the composition of amended claim 1 by (a) preparing a tooth whitening composition according to amended claim 1; (b) painting the composition onto teeth to be whitened; (c) maintaining the composition in contact with the teeth for a plurality of hours per day; and then repeating steps (b) and (c) for multiple days to thereby whiten the teeth. As discussed above, the composition of amended claim 1 is not obvious over Prosise. Diasti relates to a composition for whitening teeth comprising a resin or varnish for adhering the composition to the teeth. There is no teaching of a water-insoluble film forming agent, let alone from 5 to 30% w/w of a film-forming component consisting essentially of a water-insoluble film-forming agent which is ethyl cellulose and a solvent for the film-forming agent. Again, the hydroxy propyl cellulose taught in the examples, while a cellulose material, is water soluble. See, page 245 of the Handbook of Pharmaceutical Excipients, Third Ed. (2000), included with the Amendment filed May 30, 2008.

Therefore, one of skill in the art reading Prosise alone, or in any fair combination with Disasti, would not have been motivated to modify the teaching in Prosise to arrive at the instant invention. A *prima facie* case of obviousness has not been established. Favorable reconsideration and withdrawal of the rejection under Section 103(a) are requested.

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In view of the above remarks, favorable reconsideration of claim 1-4, 6, 9 and 10, and allowance of this application are earnestly solicited.

Respectfully submitted,

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